

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

The Effects of Benson's relaxation technique and phone Consultation on Depression and Self-esteem among pregnant women

Protocol summary

Study aim

The study was designed to determine the effect of Benson relaxation and phone counseling on Depression and Self-esteem among pregnant women.

Design

This trial has 2 intervention groups (Benson and phone counseling) and 1 control group, each group includes 27 people, with parallel groups, without blinding, randomized, on 81 patients (with Considering the fall, 90 people). For randomization, a table of random numbers is used

Settings and conduct

90 pregnant women referring to Alborz health centers with the characteristics of the research unit are selected and randomly placed in one of the 3 groups receiving phone counseling, Benson group, and control group. In the relaxation group, after one training session, the mother is asked to do relaxation for 15-20 minutes twice a day for 4 weeks. In the counseling group, counseling is given through phone counseling (for 4 weeks). Maternal depression and self-esteem in all three groups before and after the intervention with the Edinburgh and Rosenberg questionnaire will be measured.

Participants/Inclusion and exclusion criteria

Inclusion criteria: mother age 18-35 - At least fifth-grade literacy- First pregnancy-Gestational age in the third trimester (28-34 w) - Single pregnancy - having access to the Internet- Low-risk pregnancy Exclusion criteria: obvious fetal abnormalities _ stressful events (accident, etc.) during the last six months_ mental illness_ addiction to drugs_ using alcohol_ history of infertility and speech and hearing disorders

Intervention groups

1-Benson relaxation group, the mother is asked to do relaxation for 15 to 20 minutes twice a day for 4 weeks 2 - A group through counseling by phone (in such a way that during 4 sessions, one 45-60 minute session per week, related topics are held via Skype or Whats-app) 3- The control group receives routine pregnancy care

Main outcome variables

Depression and self-esteem

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210625051699N2**

Registration date: **2022-02-21, 1400/12/02**

Registration timing: **registered_while_recruiting**

Last update: **2022-02-21, 1400/12/02**

Update count: **0**

Registration date

2022-02-21, 1400/12/02

Registrant information

Name

Sahar Hasanpoor

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6551 2606

Email address

saharhasanpoor@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-12, 1400/11/23

Expected recruitment end date

2022-03-14, 1400/12/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effects of Benson's relaxation technique and phone Consultation on Depression and Self-esteem among pregnant women

Public title

Effects of relaxation Consultation on Depression and Self-esteem during pregnancy

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Mother age 18-35 At least fifth grade literacy First pregnancy Gestational age in the third trimester (28-34) weeks Single pregnancy Low risk pregnancy Having access to the Internet

Exclusion criteria:

Absence of obvious fetal abnormalities Absence of stressful events (accident, etc.) during the last six months Absence of mental illness Not using or addiction to drugs Not using psychedelics and alcohol Not having history of infertility and speech and hearing disorders

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done in a simple way using a table of random numbers. In this way, the members of the research will be numbered from 1 to 90 and we will randomly put the number of people from 1 to 90 in the table without any special order. Then a row and column from the table are randomly selected, the intersection point of the row and column is the starting point of sampling. From this point, and chosen by the researcher, we determine a direction (for example, up, down, right, or left) to read the table numbers, then we assume specific numbers for each of the study groups. For example, the numbers 1-30 enter the first intervention group (Benson) and if it is 31-60 the second intervention group (telephone counseling), the numbers 61-90 enter the control group.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Shaid Arabi Ave., Yaman Blvd., Tehran Town

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2021-07-20, 1400/04/29

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1400.088

Health conditions studied**1****Description of health condition studied**

Depression

ICD-10 code

F32.0

ICD-10 code description

Major depressive disorder, single episode, mild

Primary outcomes**1****Description**

Depression

Timepoint

Measurement of pregnancy's depression score is done before the intervention and immediately after the intervention.

Method of measurement

Edinburgh questionnaire

Secondary outcomes**1****Description**

Self-esteem

Timepoint

Measurement of pregnancy's self-esteem score is done before the intervention and immediately after the intervention.

Method of measurement

Rosenberg questionnaire

Intervention groups

1

Description

Intervention group 1: After holding a Benson relaxation training session, mothers are taught using simple and understandable sentences, and in this way, the mother is in the best position in which she feels calm. She sits or lies down, closes her eyes, in which case she chooses a word that always reminds her of peace (such as the word of the god of rain, flowers, etc.) and begins to take deep, regular breaths. It inhales through the nose and exhales through the mouth, repeating the word in the mind with each exhalation. In this position, release the muscles from the toes and continue this work to the upper muscles of the body until all the muscles are fully expanded and maintain this position for 10 to 20 minutes. We then advise the mother to refrain from changing posture immediately after the technique. For more effect, we recommend relaxing music while performing the technique. The intervention group performs exercises for 4 weeks, twice a day, and each time for 15-20 minutes at home.

Category

Behavior

2

Description

Intervention group 2: A group receives counseling through counseling with mobile software and remotely (in such a way that during 4 weekly sessions, a 45-60 minute session Related content is held via Skype or What's App), and the content of the counseling is based on the Gamble study counseling model and the strategy of this counseling includes: (Therapeutic communication between midwife and mother, in the first week, mother support and Expressing emotions in the second week, providing information in the third week, reinforcing positive thoughts and discovering appropriate solutions to reduce stress in the fourth week), which is taught to mothers virtually and remotely

Category

Behavior

3

Description

Control group: The control group receives routine pregnancy care

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Alborz Health Centers

Full name of responsible person

Sahar Hasanpoor

Street address

No.31, Azar Ave., Motahari Blvd., Karaj Town

City

karaj

Province

Alborz

Postal code

3143663471

Phone

+98 21 6551 2606

Email

saharhasanpoor77@gmail.co

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Afshin Zarghi

Street address

Yaman Ave., Blvd., Chamran highway ., TehranTown

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 2243 9781

Email

zarghi@sbmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Sahar Hasanpoor

Position

Master student of midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

No.31, Azar Ave., Motahari Blvd., Karaj Town

City

Karaj

Province

Alborz

Postal code

3143663471

Phone

+98 21 6551 2606

Email

saharhasanpoor77@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Shahnaz Tork Zahrani

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

Valiasr Ave

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 8865 5366

Email

zahraniashahnaz@yahoo.co

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Sahar Hasanpoor

Position

Master student of midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Shahd Arabi Ave., Yaman Blvd., Tehran Town

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 6551 2606

Fax

Email

saharhasanpoor77@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available